

§ 870.1370

commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a trace microsphere that was in commercial distribution before May 28, 1976. Any other trace microsphere shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 61 FR 50706, Sept. 27, 1996]

§ 870.1370 Catheter tip occluder.

(a) *Identification.* A catheter tip occluder is a device that is inserted into certain catheters to prevent flow through one or more orifices.

(b) *Classification.* Class II (performance standards).

§ 870.1380 Catheter stylet.

(a) *Identification.* A catheter stylet is a wire that is run through a catheter or cannula to render it stiff.

(b) *Classification.* Class II (performance standards).

§ 870.1390 Trocar.

(a) *Identification.* A trocar is a sharp-pointed instrument used with a cannula for piercing a vessel or chamber to facilitate insertion of the cannula.

(b) *Classification.* Class II (performance standards).

§ 870.1425 Programmable diagnostic computer.

(a) *Identification.* A programmable diagnostic computer is a device that can be programmed to compute various physiologic or blood flow parameters based on the output from one or more electrodes, transducers, or measuring devices; this device includes any associated commercially supplied programs.

(b) *Classification.* Class II (performance standards).

§ 870.1435 Single-function, preprogrammed diagnostic computer.

(a) *Identification.* A single-function, preprogrammed diagnostic computer is a hard-wired computer that calculates a specific physiological or blood-flow

21 CFR Ch. I (4-1-12 Edition)

parameter based on information obtained from one or more electrodes, transducers, or measuring devices.

(b) *Classification.* Class II (performance standards).

§ 870.1450 Densitometer.

(a) *Identification.* A densitometer is a device used to measure the transmission of light through an indicator in a sample of blood.

(b) *Classification.* Class II (performance standards).

§ 870.1650 Angiographic injector and syringe.

(a) *Identification.* An angiographic injector and syringe is a device that consists of a syringe and a high-pressure injector which are used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.

(b) *Classification.* Class II (performance standards).

§ 870.1660 Indicator injector.

(a) *Identification.* An indicator injector is an electrically or gas-powered device designed to inject accurately an indicator solution into the blood stream. This device may be used in conjunction with a densitometer or thermodilution device to determine cardiac output.

(b) *Classification.* Class II (performance standards).

§ 870.1670 Syringe actuator for an injector.

(a) *Identification.* A syringe actuator for an injector is an electrical device that controls the timing of an injection by an angiographic or indicator injector and synchronizes the injection with the electrocardiograph signal.

(b) *Classification.* Class II (performance standards).

§ 870.1750 External programmable pacemaker pulse generator.

(a) *Identification.* An external programmable pacemaker pulse generator is a device that can be programmed to produce one or more pulses at preselected intervals; this device is used in electrophysiological studies.

Food and Drug Administration, HHS

§ 870.2310

(b) *Classification*. Class II (performance standards).

§ 870.1800 Withdrawal-infusion pump.

(a) *Identification*. A withdrawal-infusion pump is a device designed to inject accurately drugs into the bloodstream and to withdraw blood samples for use in determining cardiac output.

(b) *Classification*. Class II (performance standards).

§ 870.1875 Stethoscope.

(a) *Manual stethoscope*—(1) *Identification*. A manual stethoscope is a mechanical device used to project the sounds associated with the heart, arteries, and veins and other internal organs.

(2) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

(b) *Electronic stethoscope*—(1) *Identification*. An electronic stethoscope is an electrically amplified device used to project the sounds associated with the heart, arteries, and veins and other internal organs.

(2) *Classification*. Class II (performance standards).

[45 FR 7907-7971, Feb. 5, 1980, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38796, July 25, 2001]

§ 870.1915 Thermodilution probe.

(a) *Identification*. A thermodilution probe is a device that monitors cardiac output by use of thermodilution techniques; this device is commonly attached to a catheter that may have one or more probes.

(b) *Classification*. Class II (performance standards).

Subpart C—Cardiovascular Monitoring Devices

§ 870.2050 Biopotential amplifier and signal conditioner.

(a) *Identification*. A biopotential amplifier and signal conditioner is a device used to amplify or condition an electrical signal of biologic origin.

(b) *Classification*. Class II (performance standards).

§ 870.2060 Transducer signal amplifier and conditioner.

(a) *Identification*. A transducer signal amplifier and conditioner is a device used to provide the excitation energy for the transducer and to amplify or condition the signal emitted by the transducer.

(b) *Classification*. Class II (performance standards).

§ 870.2100 Cardiovascular blood flowmeter.

(a) *Identification*. A cardiovascular blood flowmeter is a device that is connected to a flow transducer that energizes the transducer and processes and displays the blood flow signal.

(b) *Classification*. Class II (performance standards).

§ 870.2120 Extravascular blood flow probe.

(a) *Identification*. An extravascular blood flow probe is an extravascular ultrasonic or electromagnetic probe used in conjunction with a blood flowmeter to measure blood flow in a chamber or vessel.

(b) *Classification*. Class II (performance standards).

§ 870.2300 Cardiac monitor (including cardi tachometer and rate alarm).

(a) *Identification*. A cardiac monitor (including cardi tachometer and rate alarm) is a device used to measure the heart rate from an analog signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits.

(b) *Classification*. Class II (performance standards).

§ 870.2310 Apex cardiograph (vibrocardiograph).

(a) *Identification*. An apex cardiograph (vibrocardiograph) is a device used to amplify or condition the signal from an apex cardiographic transducer and to produce a visual display of the motion of the heart; this device also provides any excitation energy required by the transducer.

(b) *Classification*. Class II (performance standards).